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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,571	02/16/2006	Yutaka Akahori	9319A-001559/US/NP	6474

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HARNESS, DICKEY & PIERCE, P.L.C.
P.O. BOX 828
BLOOMFIELD HILLS, MI 48303

EXAMINER	
COMLEY, ALEXANDER BRYANT	
ART UNIT	PAPER NUMBER
3746	
MAIL DATE	DELIVERY MODE
08/22/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,571	AKAHORI, YUTAKA	
	Examiner	Art Unit	
	ALEXANDER B. COMLEY	3746	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 February 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/16/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. **Claim 5** is objected to because of the following informalities: The phrase "by differentiating sizes of the two cams each other" appears to be missing a word. Appropriate correction is required.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "other opening/closing mechanism" (**Claim 21**) and the "valve" (**Claim 22**) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claims 1-20** are rejected under 35 U.S.C. 102(b) as being anticipated by United States Patent No. 5,217,355 to Hyman et al. directed to a Two-Cycle Peristaltic Pump with Occlusion Detector.

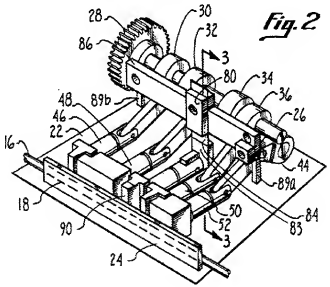


Fig. 2

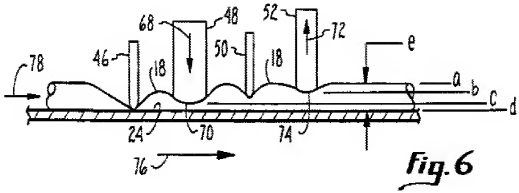


Fig. 6

In regards to Independent **Claim 1**, and with particular reference to Figures 2 & 6 shown immediately above, Hyman et al. (5,217,355) discloses:

(1) A tube pump (10) for transferring a fluid, comprising: a tube (16) defining a flow path therein through which the fluid is transferred, the tube (16) being capable of being deformed elastically, the tube (16) having two opening/closing portions provided at two spaced portions of the tube (16) for opening and closing the flow path; and two opening/closing mechanisms (32, 36) which are provided so as to correspond to the two opening/closing portions respectively for closing the flow path at the two spaced portions of the tube (16) by folding the corresponding opening/closing portion of the tube (16) and opening the flow path by unfolding the fold of the opening/closing portion; wherein, when one of the two opening/closing portions is further folded after closing the flow path at the corresponding portion of the tube (16) by operating the corresponding opening/closing mechanism (48) in a state where the other opening/closing portion is folded, an internal pressure in the tube (16) between the two

opening/closing portions is increased due to the further fold of the opening/closing portion, and the tube pump (10) transfers the fluid using the increased internal pressure in the tube (16).

(14) A tube pump (10) for transferring a fluid, comprising: a tube (16) defining a flow path therein through which the fluid is transferred, the tube (16) being capable of being deformed elastically, the tube (16) having two opening/closing portions provided at two spaced portions of the tube (16) for opening and closing the flow path, and the two opening/closing portions being arranged so as to face to each other through a predetermined space therebetween; and an opening/closing mechanism (32, 36; 48, 52) provided in the space between the two opening/closing portions for closing the flow path at the portion corresponding to each of the two opening/closing portions by folding the tube (16) at the opening/closing portion and for opening the flow path by unfolding the fold of the opening/closing portion; wherein, when one of the two opening/closing portions is further folded after closing the flow path at the corresponding portion of the tube (16) by operating the opening/closing mechanism (32, 36; 48, 52) in a state where the other opening/closing portion is folded, the degree of fold of one opening/closing portion becomes differentiated from that of the other opening/closing portion so that an internal pressure of the tube (16) between the two opening/closing portions is increased due to the further fold of the

opening/closing portion, and the tube pump (10) transfers the fluid using the increased internal pressure of the tube (16).

As best shown in Figure 2 above, Hyman discloses a peristaltic pumping device that is utilized for precisely metering the flow of medical fluids to a patient. The tube has various opening/closing portions spaced along it's length, and the closing mechanisms are disposed therebetween. Hyman's pump utilizes different sized reciprocating fingers (48, 52) in order to maintain increased internal pressure within the tube. The fingers are reciprocated by a rotating camshaft with four individual cams corresponding to the four individual fingers. In particular, Hyman states "Each cam 30, 32, 34 and 36 contacts a corresponding linkage. Only linkage 44, which is associated with cam 36, is shown in FIG. 2. The cams 30, 32, 34 and 36 against the respective linkages and thereby drive pump fingers 46, 48, 50, and 52 respectively." (Column 4, Lines 55-62) As best seen in Figure 6 above, the pumping fingers (48, 52) are sized differently in order to pump different amounts of fluid through the tube, and consequently, provide increased pressure therein. In particular, Hyman states "With respect to the description of the invention herein, "large" and "small" describe pumping fingers which are constructed to move against tube portion 18 such that the amount of fluid displaced as "large" finger 48 moves downward against tube 18, is approximately two (2) times that displaced by an equal reciprocal downward motion of "small" finger 52. It is important to note that the reciprocal motion of fingers 48 and 52 is generally equal in range, but that in the fully extended position, the pumping fingers 48, 52 do not ever fully occlude the tubing."

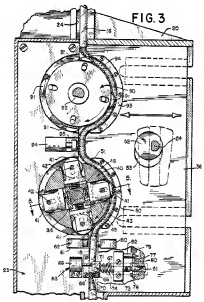
(Column 5, Lines 58-68) Consequently, it is clear from this disclosure that the finger 48 provides an increased internal pressure within the tube due to its increased size.

5. In regards to dependent **Claims 2-4 & 15,** it is clear from Figures 2 and 6 that the mechanisms 48 and 52 are of different sizes in order to generate the increased internal pressure within the tube (See Column 5, Lines 58-68) Furthermore, Figure 2 best shows how the curved portions of the tube are folded through the pushing of the pumping fingers (48, 52) by their corresponding cam portions (32, 36). In regards to dependent **Claims 5-6,** the fingers (46, 48, 50, 52) and the cams (30, 32, 34, 36) form the cam mechanisms that each press against the tube and force fluid therethrough. The fingers (48, 52), as seen in Figure 6, are sized differently from one another in order to provide increased fluid flow while the cams (30, 32, 34, 36), as also seen in Figure 2, are semi-circular in shape. In regards to dependent **Claims 7-10 & 18**, the fingers/linkages of each cam mechanism are disposed on a base plate 22 and form a reciprocating frame that is driven by the cams (30, 32, 34, 36). As the cams are rotated, the frames are reciprocated toward and away from the tubing by the action of the rise and dwell of the cams, as well as the by resilient action of the tube itself. The cams' dwell portions each serve to help bias the frame away from the tubing and release the fold applied thereto. In such a linkage, the fingers act as the direct connection between the tube closing portions and the frame. Regarding dependent **Claims 11-13 & 19-20**, Figures 2 best shows that the pump of Hyman utilizes a platen (i.e. fixing jig) to position the tube upon the base. In particular, Hyman states "The components of

peristaltic pump apparatus 10 can be best appreciated with reference to FIG. 2, where it will be seen that peristaltic pump apparatus 10 includes a base 22 which has a generally flat platen 24 Platen 24 provides a surface against which portion 18 (shown in phantom in FIG. 2) of tube 16 may be occluded." (Column 4, Lines 49-54) Obviously, adjustment of this platen, or jig, directly affects the amount of compression applied by the adjacent cam mechanisms. Furthermore, Hyman discloses that the pinching fingers (46, 50) alternately fully occlude/fully open the flow tube. In particular, Hyman states "As can be appreciated from the disclosure above, and again referring to finger 46 as an example, the reciprocating motion of finger 46 causes it to alternately press against and withdraw from tube portion 18. Finger 46 thereby alternately occludes and opens tube portion 18." (Column 5, Lines 31-36) Consequently, the flow path is always closed by one of the two pinching fingers fully occluding the tube. In regards to dependent **Claims 16-17**, Applicant's "stepped cam" is taught by Hyman's cam/linkage/finger mechanism (See Figure 2). In particular, Hyman's mechanism comprises four separate semicircular cams (i.e. cam portions) that actuate linkages (i.e. arms) in order to reciprocate differently sized fingers (i.e. actuators). The outer peripheral surfaces of each cam rotates to convert rotational motion into linear reciprocating motion in order to bring each of the linkages (i.e. arms) and fingers (i.e. actuators) into physical contact with the opening/closing portions of the tube. Hyman states "Mounted on base 22 is a rotatable shaft 26, which is driven by a motor (not shown) that engages with gear 28. Shaft 26 also includes cams 30, 32, 34 and, 36. Each cam 30, 32, 34 and 36 contacts a corresponding linkage. Only linkage 44, which is associated with cam 36, is shown in

FIG. 2. The cams 30, 32, 34 and 36 against the respective linkages and thereby drive pump fingers 46, 48, 50, and 52, respectively." (Column 4, Lines 55-62) Hence, the different sized, co-rotating fingers of Hyman's stepped cam mechanism provide tube folding in a "stepwise manner" in order to produce efficient fluid flow through the tube.

6. **Claims 21-22** are rejected under 35 U.S.C. 102(b) as being anticipated by United States Patent No. 4,278,085 to Shim directed to a Method and Apparatus for Metered Infusion of Fluids.



In regards to Independent **Claim 21**, and with particular reference to Figure 3 shown immediately above, Shim discloses:

A tube pump (23) for transferring a fluid, comprising: a tube (18) defining a flow path therein through which the fluid is transferred, the tube (18) being capable of being deformed elastically, the tube (18) having two opening/closing portions provided at two spaced portions of the tube (18) for opening and closing the flow

path; and two opening/closing mechanisms (40, 90; 63) which are respectively provided so as to correspond to the two opening/closing portions, one of the opening/closing mechanisms (40, 90) closing the flow path at one of the two spaced portions of the tube (18) by folding the corresponding opening/closing portion of the tube (18) and opening the flow path by unfolding the fold of the opening/closing portion, and the other opening/closing mechanism (63) closing and opening the flow path at the other portion of the tube (18) without folding and unfolding the corresponding opening/closing portion of the tube (18); wherein, when the opening/closing portion is further folded after closing the flow path at the corresponding portion of the tube (18) by operating the corresponding opening/closing mechanism (40, 90) in a state where the other opening/closing portion is closed, an internal pressure in the tube (18) between the two opening/closing portions is increased due to the further fold of the opening/closing portion, and the tube pump (23) transfers the fluid using the increased internal pressure in the tube (18).

As shown in Figure 3 above, Shim discloses an infusion device for use in the medical field that is utilized to pump medicinal fluids to a patient through a compressible flow tubing. Two mechanisms are also provided in Shim's pump. The two tube-folding rotors (40, 90) provide one of the mechanisms, while the flow restriction station 63 provides the other mechanism. The first mechanism is described by Shim in stating "Referring to FIG. 3, the fluid control station 23 includes metering means in the form of a rotor 40 mounted for rotation on a shaft 39 and having four pressure rollers 41 disposed

in equi-spaced relationship about its circumference. The rollers are each mounted on a shaft 42 for free rotation, and the shaft are carried on individual carriages 43 mounted on the rotor for reciprocation within a radial recess 45. The carriages are each spring-biased in a radially outward direction by helical springs 46 disposed within the recesses." (Column 4, Lines 11-21) Shim's first mechanism further utilizes upline pressurization means to provide increased internal pressure within the flow tubing. In particular, Shim states "Referring again to FIG. 3, in the illustrated embodiment upline pressurization means in the form of a second or additional rotor 90 is provided. This rotor is mounted for rotation on a drive shaft 92, and includes four pressure rollers 91 equi-spaced about its circumference. Pressure rollers 91 may be mounted for radial reciprocation relative to the rotor in the same manner as pressure rollers 41. A second pressure plate 93 having an arcuate working surface 94 corresponding generally to the circumference of rotor 90 is mounted on platen assembly 36 so as to bring tubing 18 into successive compressive engagement with pressure rollers 91 as rotor 90 rotates. Thus, rotor 90 and pressure plate 93 together form a peristaltic-type pump for pressurizing fluid in tubing 18 upline of the point of engagement of pressure rollers 41." (Column 5, Lines 42-57) Moreover, Shim's device also comprises a flow restriction station 63 (i.e. valve) that functions to close off, or restrict, flow through the tubing. In particular, Shim states "The tubing then passes through downline pressurization means in the form of a flow restriction station 63. This station includes a slidably-mounted plunger 67 which is biased against the sidewall of tubing segment 18. The end of plunger 67 which engages the tubing segment includes a generally L-shaped head

portion 68 having a wedge-shaped working surface 70 which occludes the tubing and a generally flat control surface 71 on which the fluid acts. The central body portion of the plunger is slidably received within a stationary mounting block 73, are extends through the center of a helical compression spring 74 which biases head 68 into engagement with the tubing." (Column 4, Lines 44-56) In contrast to the first mechanism (40, 90) which applies a rolling/folding function to the tubing, the flow restriction station 63 merely compresses the tubing to restrict flow, and does not actually fold the tubing to provide this restriction.

7. In regards to dependent **Claim 22**, it is clear that the flow restriction station 63 (i.e. the other opening/closing mechanism) acts as a valve.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following selected patents and technical literature is cited to further show the state of the art in tube pumps and related technology in general where the not all obvious salient features of the patents are disclosed as follows:

- US Patent No. 4,856,972 to Van Benschoten et al. discloses a peristaltic pump that utilizes dual rollers to compress a flexible tubing and provide improved flow characteristics

- US Patent No. 5,165,873 to Meijer provides a two-stage peristaltic pump that utilizes different sized cam portions to create better flow through the tubing

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEXANDER B. COMLEY whose telephone number is (571)270-3772. The examiner can normally be reached on M-F 7:30am - 5:00am EST (Alternate Fridays Off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Devon C. Kramer can be reached on (571)-272-7118. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alexander B Comley/
Examiner, Art Unit 3746

/Devon C Kramer/
Supervisory Patent Examiner, Art Unit 3746

ABC